IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

IN RE: GERBER PRODUCTS COMPANY HEAVY METALS BABY FOOD LITIGATION	Master File No. 1:21-cv-00269 (MSN/JFA)
This Document Relates to ALL Cases	

DECLARATION OF NEGA BERU, Ph.D. IN SUPPORT OF GERBER PRODUCTS COMPANY'S MOTION TO DISMISS REPRESENTATIVE CLASS ACTION COMPLAINT

1. I, Nega Beru, Ph.D., submit this declaration in support of Gerber Product Company's Motion to Dismiss the Representative Class Action Complaint. In preparing this declaration, I reviewed FDA's public statements following the February 4, 2021 staff report issued by the Subcommittee on Economic and Consumer Policy of the U.S. House of Representatives' Committee and materials pertaining to its "Closer to Zero" Action Plan discussed below. Unless otherwise noted, I have personal knowledge of the following facts and, if called as a witness, I could and would testify competently thereto.

2. I served at the United States Food and Drug Administration for 26 years, until my retirement in 2017. I joined FDA in 1991 and began my career in the Office of Food Additive Safety. From 1999 to 2004, I served as Director of the Division of Plant Product Safety in the Office of Plant and Dairy Foods. From 2005 to 2006, I served as Associate Director of the Office of Plant and Dairy Foods (currently known as the Office of Food Safety). From 2006 to 2017, I served as Director of the Office of Food Safety in the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN). From 2007 to 2015, I also served as head of the U.S. Delegation to the Codex Committee on Contaminants in Food, a subsidiary body of Codex

Alimentarius Commission, an international organization established by the United Nations' World Health Organization and the Food and Agriculture Organization. Codex Alimentarius Commission promotes the adoption of global food standards, codes of practice, and other guidelines to protect the health of consumers and ensure fair practices in the food trade. A true copy of my CV is attached hereto as **Exhibit A**.

3. FDA's Center for Food Safety and Applied Nutrition is dedicated to carrying out FDA's mission to protect public health by ensuring the safety of the U.S. food supply. Specifically, CFSAN is responsible for modernizing methods to find, track, reduce, and/or eliminate contaminants in food, evaluating the safety of ingredients in food, evaluating and improving manufacturing practices, ensuring proper labeling for food, fostering healthy and safe nutrition, investigating causes of potential harms associated with food, and targeting unsafe products. As Director of the Office of Food Safety, I led approximately 200 experts in food safety, many with doctorates in a wide variety of fields, including toxicology, epidemiology, chemistry, microbiology, and many other scientific disciplines related to food safety. FDA's CFSAN has a broad mandate, and is responsible for safeguarding the safety of more than $1.5 trillion worth of food, cosmetics, and dietary supplements.

4. FDA has been monitoring and testing trace levels of metals in baby foods for many years. Throughout my tenure, FDA routinely monitored levels of various elements in baby foods and, where necessary, took regulatory or enforcement action. FDA also set action levels for particular foods.

5. While at FDA, I was personally involved in the process of setting action levels for foods consumed by infants and children. In particular, in 2016, I served on the Risk Management Team overseeing FDA's risk assessment for inorganic arsenic in rice, which served as the scientific

basis for FDA issuing action levels for inorganic arsenic in rice cereal for infants. I also worked on FDA's issuance of action levels for lead in certain candies, and for inorganic arsenic in apple juice. I therefore have personal knowledge of the tremendous resources, technical expertise, feasibility analyses, and stakeholder outreach required for FDA to appropriately and prudently set action levels in this area.

6. On February 4, 2021, the Subcommittee on Economic and Consumer Policy of the U.S. House of Representatives' Committee issued a staff report regarding levels of heavy metals in baby foods ("Staff Report") and warning consumers that baby foods might be "unsafe." FDA promptly issued its initial response to the Staff Report on February 16, 2021. FDA did not endorse the Staff Report or support its findings. To the contrary, FDA made several public statements ***contradicting*** the conclusions drawn by the authors of the Staff Report. Indeed, FDA "reassure[d] parents and caregivers" that "children are not at an immediate health risk from exposure to [heavy metals] in foods" and provided important advice that FDA "does not advise parents and caregivers to throw out their supply of packaged baby foods or to stop feeding their babies and children certain foods altogether" because "[e]liminating food groups from your children's diet in order to avoid certain toxic elements that occur in the food supply may result in deficiencies in certain nutrients and potential poor health outcomes." **Exs. 1-2**.[1]

7. On April 8, 2021, only two months after the issuance of the Staff Report, FDA announced its "Closer to Zero" Action Plan for Reducing Exposure to Toxic Elements from Foods for Babies and Young Children ("Action Plan"). **Exs. 3-4.**

8. FDA's Action Plan is an unprecedented and extraordinary mobilization of

[1] To avoid duplication, all references to numbered exhibits herein are to the exhibits to the Declaration of Bryan A. Merryman in support of Gerber's motion to dismiss.

resources to determine safe levels of lead, inorganic arsenic, cadmium, and mercury in foods for babies and young children. FDA has set forth a detailed plan to address these naturally occurring elements across all products consumed by babies and young children. FDA's Action Plan is an enormous undertaking, and FDA has established an expedited schedule to research, analyze, and issue action levels to reduce the levels of heavy metals in foods without causing unintended consequences, such as eliminating nutritious foods from the market, creating consumer confusion, and causing nutrient deficiencies in children. FDA's Action Plan stands out for the level of targeted attention and expenditure of resources FDA is devoting to this specific food safety issue at this time.

9. Indeed, FDA already set draft action levels for lead in juice in April 2022, and has publicly reaffirmed its commitment to its expedited schedule to set action levels for lead, inorganic arsenic, cadmium, and mercury in baby foods.

10. The scientific and technical challenges posed by these issues are substantial. Lead, inorganic arsenic, cadmium, and mercury are very different elements, have different toxicological profiles, and can have different potential effects depending on the exposure level, duration, and myriad other factors. These heavy metals occur naturally in baby foods at very small levels, measured in parts per billion, and levels vary from one baby food to the next. Although FDA has been studying heavy metals in the food supply for years, there is still little research into whether heavy metals create any health risks at the very low levels they are found in baby foods. In order to research, evaluate, and provide guidance on action levels to reduce levels of heavy metals in baby foods, FDA will need to conduct its own testing and research, develop new models to understand and evaluate data, and synthesize information from a wide variety of sources.

11. FDA is ***obligated*** to consider the feasibility and achievability of any action levels

or other guidance it issues. When confronted with complex issues like reducing levels of naturally occurring heavy metals in baby foods, FDA must weigh the various health, safety, and policy considerations at issue before making a determination.

12. Here, there is no simple solution to reduce heavy metals in baby foods. As FDA has repeatedly informed the public, heavy metals naturally occur in air, water, and soil and are taken up in the growing process by fruits, vegetables, and grains used in baby foods. Regulating levels of heavy metals is not only a food safety issue, it affects agriculture, nutrition, health and medicine, domestic and international commerce, environmental health, and many other fields.

13. For example, before setting action levels for any specific baby food, FDA needs guidance and input from USDA on what, if any, agricultural practices exist to further reduce the levels of heavy metals. As another example, the USDA's Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC") provides assistance to low-income families, including by providing free and low-cost baby foods. Setting action levels for baby food products at unfeasible and unachievable levels could negatively impact public availability of foods to low-income communities through programs such as WIC.

14. Before enacting final action levels or issuing guidance affecting the U.S. food supply, FDA works hard with a variety of stakeholders to identify and mitigate against these types of unintended consequences. Indeed, FDA is required to initially publish action levels in draft form, and then to allow input from all stakeholders before they are finalized, ensuring that all perspectives are accounted for and that all relevant considerations can be detected and weighed fairly.

15. FDA's Action Plan will require input, guidance, research, and data from many stakeholders, such as the USDA, the U.S. Environmental Protection Agency, the National Center

for Toxicological Research, the National Institute of Environmental Health Sciences, the CDC's Agency for Toxic Substances and Disease Registry, physicians, advocacy groups, manufacturers, industry, and others

16. In addition, the presence of trace levels of heavy metals in foods is not limited to the United States; it is a global food supply issue that implicates U.S. imports, exports, and international commerce. FDA therefore regularly consults and works with various multinational organizations, including the Food and Agriculture Organization and the World Health Organization of the United Nations and subsidiary bodies such as the Codex Committee on Contaminants in Food and the Joint Expert Committee on Food Additives in formulating its determinations on these issues.

17. FDA relies on its considerable and wide-ranging resources, technical expertise, and partners to determine what levels of heavy metals in baby foods renders them unsafe and to ensure its determinations do not result in unintended consequences that could cause harm to infants and young children. CFSAN is directing tremendous resources to this particular issue affecting the health and safety of infants and young children, and its Action Plan is proceeding under an accelerated timeline to issue guidance and feasible action levels.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on this 7th day of July, 2022, at Washington, D.C.

Nega Beru, Ph.D.

CERTIFICATE OF SERVICE

I hereby certify that on July 8, 2022, I caused a copy of the foregoing **DECLARATION OF NEGA BERU, Ph.D. IN SUPPORT OF GERBER PRODUCTS COMPANY'S MOTION TO DISMISS REPRESENTATIVE CLASS ACTION COMPLAINT** to be filed electronically with the Clerk of the Court via the Court's ECF system, which will send notification of such filing to all counsel of record.

By: */s/ Kathryn J. Mims*

Kathryn J. Mims (Va. 81486)
WHITE & CASE LLP
701 Thirteenth Street, NW
Washington, DC 20005
T: (202) 626-3704
F: (202) 639-9355
kmims@whitecase.com

Attorneys for Defendant
Gerber Products Company